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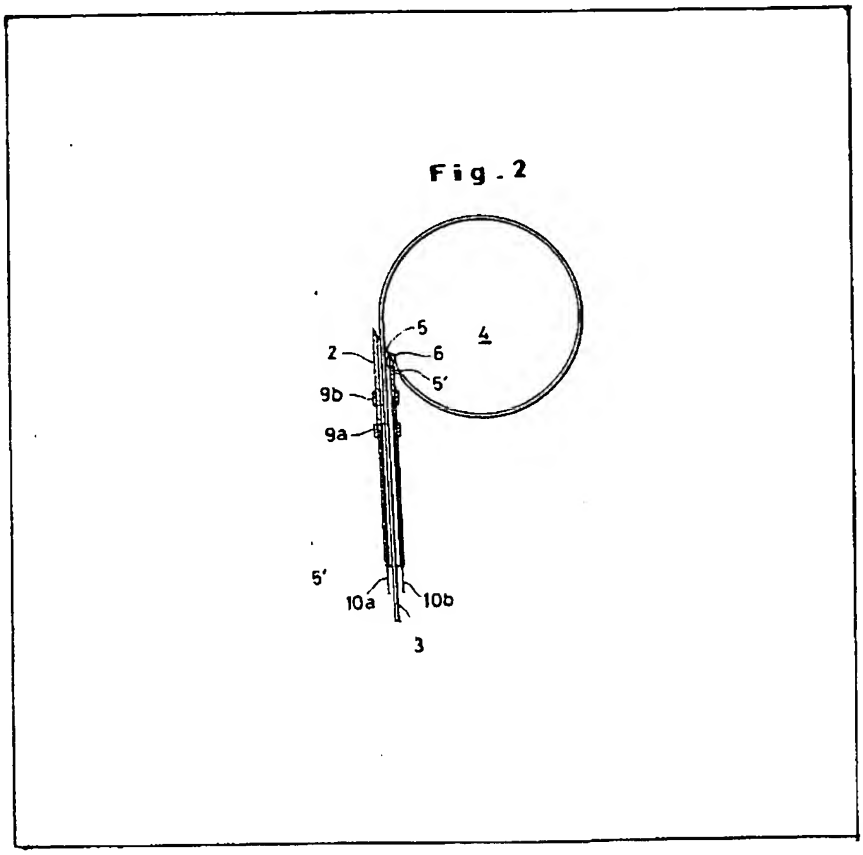
(54) **Device for use in heart pacer electrode fixation**

(57) A catheter device for use in atrial pacer electrode fixation has electrodes 9*a* 9*b* for determining the optimum electrode position, and a wire 3 extending along the bore of an outer tube 2 with the leading ends of wire 3 and tube 2 connected 6 so that pushing wire 3 forms a loop 4 therein. The catheter is transvenously inserted into the right atrium and moved to various positions to determine the optimum atrial pacing electrode position and the loop 4 is then formed whereafter a double lumen needle 12 with a folded steel wire 13 therein is inserted into the right atrium via the chest wall so that the leading end of wire 13 is located in the loop 4. After wire 3 is pulled to tighten the loop 4 around wire 13, the catheter is withdrawn from the body pulling the leading end of wire 13 with it. Wire 13 is then detached from loop 4, attached to a permanent pervenous electrode assembly 14, 14', and drawn back into the right atrium until the leading end of this electrode assembly abuts the needle 12 which is then withdrawn from the body and the electrode assembly retained in position by subcutaneous suturing 15.



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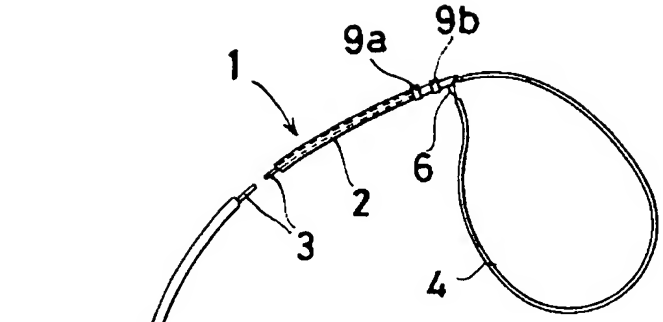

Fig. 1

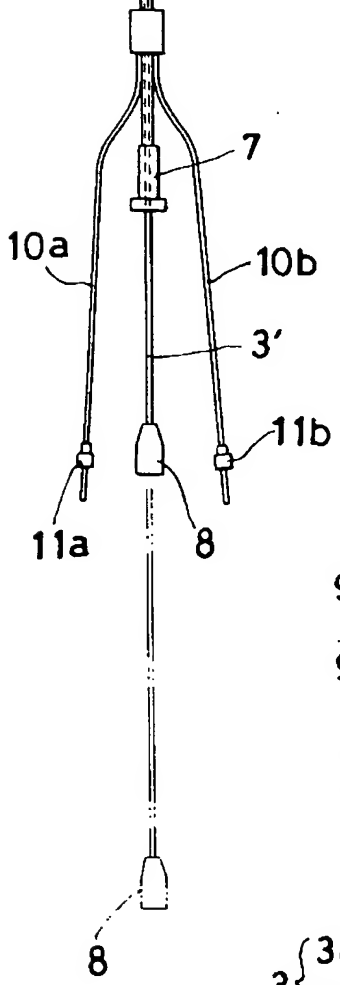

Fig. 2

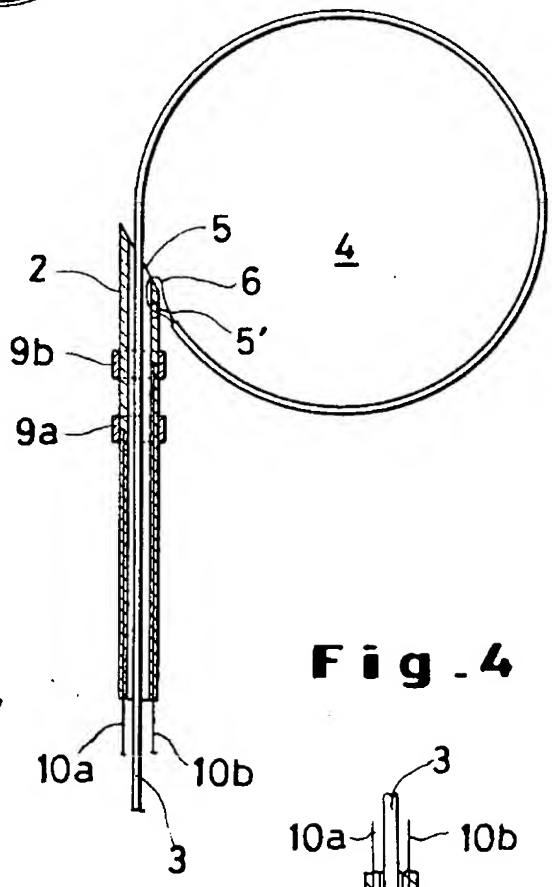

Fig. 3

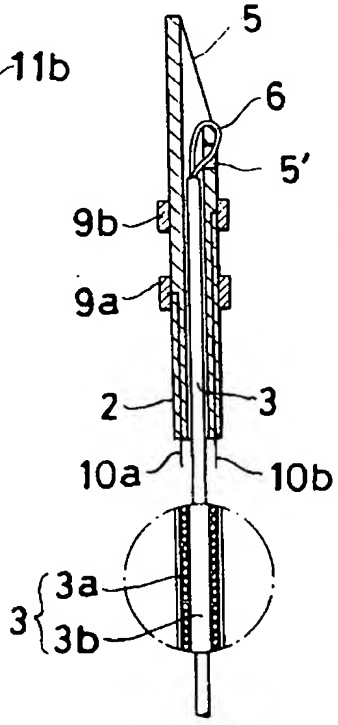

Fig. 4

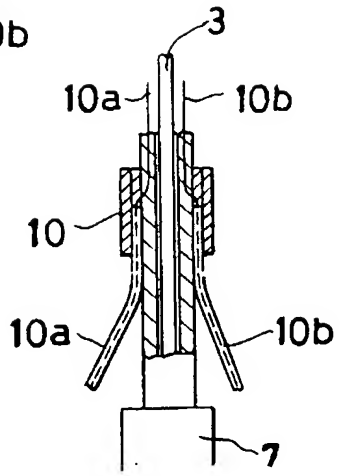

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Fig_5

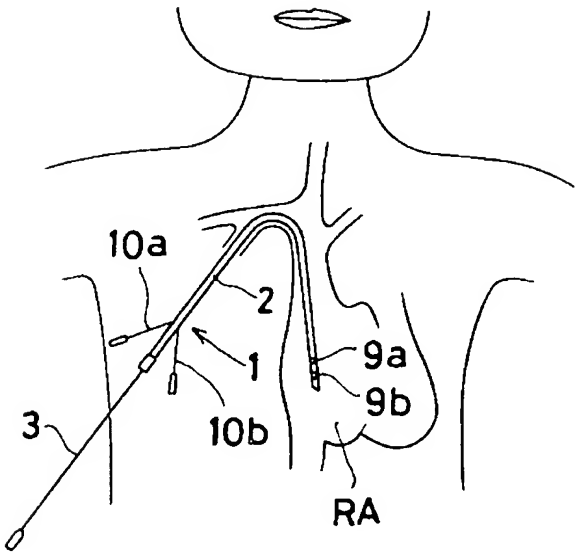

Fig_6

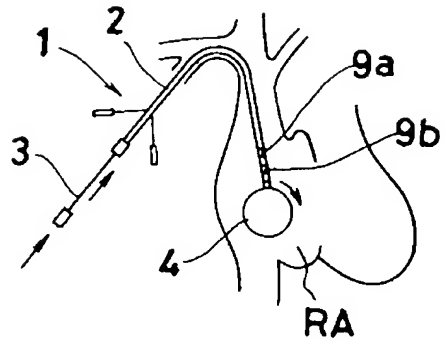

Fig_7

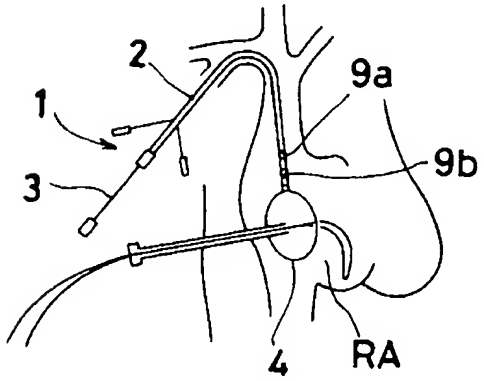

Fig_8

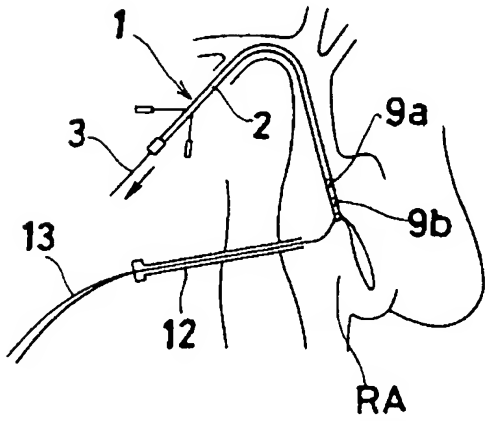

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Fig_9

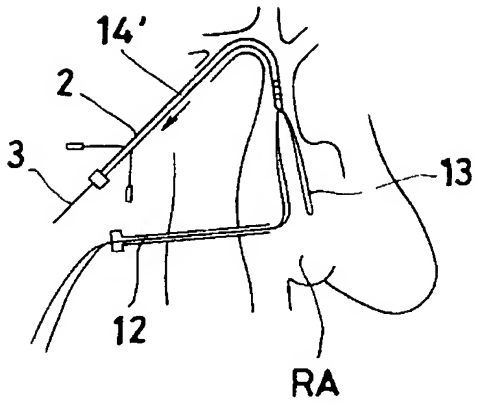


Fig_10

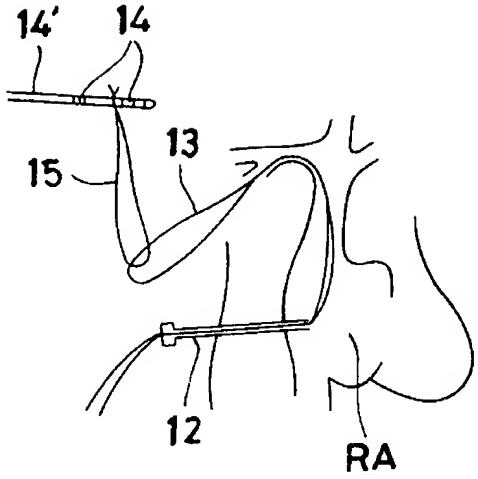


Fig_11

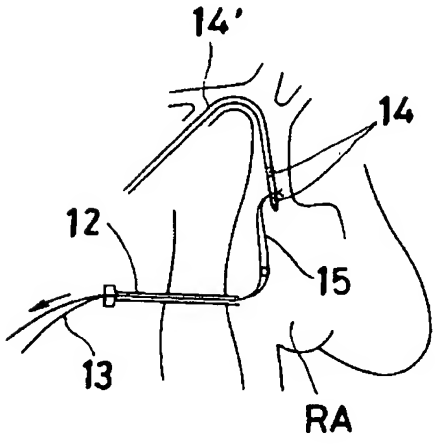
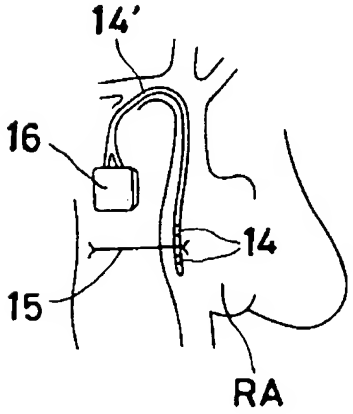


Fig_12



SPECIFICATION

Method for fixing pervenous electrode in atrial pacing and device therefor

Description

This invention relates to a method for easy and safe fixation of a pervenous electrode at the optimum position within the right atrium for treatment of arrhythmia through the electrical stimulation of the affected heart and to a device used for the fixation mentioned above.

The pacemakers of the kind which require that electrodes for delivering rhythmical electrical stimuli be fixed within the atrium include the P-synchronized pacemaker, the bifocal demand pacemaker, the fixed-rate pacemaker, the demand pacemaker and the radio-frequency induced atrial pacemaker.

The electrodes for delivering electrical stimulating pulses from pacemakers to the atrium are broadly grouped by the method of fixation thereof into two types: Myocardial electrodes which are fixed as by thoracotomy and allowed to generate electrical stimuli epicardially and pervenous electrodes which are fixed after insertion through the incised subclavian vein and allowed to generate electrical stimuli endocardially. The myocardial electrodes are highly susceptible to surgical incursions and, therefore, are not suitable for use on senile patients and poor risk patients unable to endure surgery. The present invention relates to a method for the endocardial stimulation by use of a pervenous electrode.

The methods which have heretofore been developed for the pevenous fixation of electrodes in the right atrium include those involving insertion of a J-shaped lead or an anchored electrode in the right atrial appendages and those involving insertion of a pervenous electrode in the coronary sinuses, for example. In all these conventional methods, since the electrodes are not sutured to the endocardium, there is a possibility of the electrodes being detached from the positions of the endocardium where they were initially fixed, with the result that the pacemakers will fail to provide required pacing and sensing actions.

The inventor, therefore, performed clinical trials in search of a way of improving the conventional methods described above. On the basis of the outcomes of the clinical trials, the inventor perfected a method for safe fixation of the pervenous electrode at the optimum position with the right atrium to provide required atrial pacing in a given case. At the 30th general meeting of the Japanese Association for Thoracic Surgery held on September 25, 1977, the inventor published this method. He further published this method in medical journals, specifically in the February, 1978 and August, 1978 issues of the "Japanese Journal of Thoracic Surgery" and in the "Journal of the Japanese Association for Thoracic Surgery", Vol. 26, No. 8.

The gist of the publication is as follows:

The subclavian fossa of a given patient is subjected to skin incision to expose the right cepharic vein and an inspector catheter for potential detection is inserted through the vein into the right atrium. The right atrium is explored with the inserted catheter to determine the optimum positon of a permanent pevenous electrode through measurement of the stimulating thresholds and endocardial potentials in the anterior and lateral walls of the right atrium. When the optimum position is found, the pervenous electrode is extracted. Then in the same manner, the electrode is inserted into the right atrium and brought to the predetermined optimum positon under fluoroscopic observation and fixed at that optimum position. This technique accomplishes the fixation of the pervenous electrode within the right atrium on the basis of the conventional method followed in the fixation of the electrode within the right ventricle in ventricular pacing. This method unfortunately requires more time and labor and higher surgical skill.

An object of the present invention, therefore, is to provide a method for ready fixation of the pervenous electrode at the optimum position, with ample saving in the time and labor required for the fixation of the electrode in the endocardium in the atrial pacing, and a device to be used for practicing the method described above.

To accomplish the object described above according to the present invention, there is provided a method, which comprises inserting into the right atrium an inspection catheter provided with a slidably built-in guidewire to explore the endocardium of the right atrium and determine the optimum position for a pervenous electrode, causing the guidewire to be forced out of the inspection catheter and allowed to form a loop within the right atrium, piercing a double lumen needle through the chest wall in the direction of the loop of guidewire, passing a induction steel wire through the double lumen needle until the leading end of the steel wire emerges past the loop into the interior of the right atrium, drawing the guidewire and thereby causing it to contract round and catch firm hold of the inserted end of the steel wire, then withdrawing completely the inspection catheter with the end of contracted loop of the guidewire, replacing the inspection catheter with a pervenous electrode, drawing the tail end of the steel wire remaining on the outer exposed side of the double lumen needle pierced through the chest wall until the pervenous electrode is brought into the endocardium of the right atrium and thereafter a sutural thread fixed to the pervenous electrode is withdrawn all the way through the skin and sutured on the subcutaneous tissue to keep the electrode attached tightly on the endocardium of the right atrium.

Although the method of the invention necessitates advanced surgical technique on the part of the surgeon in the process in which the inspection catheter designed for detection of endocardial potential is introduced inside the right atrium and operated to explore the endocardium of the right atrium and determine the optimum position for the permanent pervenous electrode, it enjoys an advantage that, once the optimum position is determined, the fixation of the pervenous electrode can be accomplished with a comparatively simple techni-

que, the step of again guiding the pervenous electrode to the predetermined optimum position and fastening it to the optimum position, which has proved to be the most troublesome work in the conventional surgical technique is no longer required and the possibility of exposing the patient to surgical incursion is minimized.

The method of this invention can be practiced by using an inspection catheter which comprises a slender outer tube, a guidewire slidably built in the outer tube and tied to the leading end of the tube and a double lumen needle which is adapted to introduce an induction steel wire doubly folded into the right atrium.

The other objects and characteristic features of the present invention will become apparent from a detailed description of the invention to be given hereinafter with reference to the accompanying drawing.

Figure 1 is a partially cutaway overall view of one preferred embodiment of the inspection catheter for the detection of endocardial potential according to the present invention.

Figures 2 and *3* are sectioned views showing in detail the leading end of the catheter of Figure 1 in the states assumed respectively after and before the guidewire forms a loop.

Figure 4 is an enlarged sectioned view of the tail end of the catheter of Figure 1.

Figures 5-12 are explanatory diagrams showing the steps which are involved in working the method of this invention for the fixation of the pervenous electrode inside the right atrium in the order in which they are performed.

The method of the present invention for the fixation of the pervenous electrode in the atrial pacing necessitates use of an inspection catheter designed for the detection of endocardial potential, a pervenous electrode designed for permanent fixation onto the endocardium of the right atrium, a double lumen needle adapted to pierce through the chest wall into the right atrium and an induction steel wire doubly folded.

First, the inspection catheter designed for the detection of endocardial potential will be described with reference to Figures 1 through 4.

This catheter 1 is used for the purpose of determining the optimum position for the fixation of the pervenous electrode inside the right atrium by detecting the stimulating threshold through probing contact of the anterior and lateral walls of the right atrium and by measuring the endocardial potential. As illustrated, the inspection catheter comprises a long slender outer tube 2 and a flexible guidewire 3 slidably passing through the outer tube, with the leading end of the guidewire 3 tied to the leading end of the outer tube. When the rear portion 3' of the guidewire 3 which extends outwardly from the tail end of the outer tube is pushed into the outer tube in the same way as in a release cable for a camera, the leading portion of the guidewire 3 is pushed out of the leading end of the outer tube. In the guidewire, a fine steel wire 3b provides support from inside for a covering tube of a coiled wire 3a and helps the covering tube 3a slide smoothly inside the outer tube 2 at the time that the catheter is put to use. The fine steel wire 3b further serves the purpose of expanding the loop 4 which the guidewire 3 forms outside the leading end of the outer tube 2 when the rear portion of the guidewire is pushed into the outer tube.

A tough, very thin string 6 is passed through the opening of an obliquely cut end 5 of the outer tube 2 and a hole 5' perforated immeditely behind the base of the cut end and the opposite ends of this thin string 6 are secured to the leading end of the covering tube 3a. The leading ends of the outer tube 2 and the guidewire 3 are united to each other in the manner just described. At the tail ends of the outer tube 2 and the guidewire 3, there may be provided squeezing pierces 7, 8 similar to those in a release cable for a camera to facilitate the operation of the inspection catheter. The squeezing pieces 7, 8 are desired to be made of a plastic material to preclude adhesion of blood.

When the rear portion 3' of the guidewire 3 which extends outwardly from the tail end of the outer tube 2 is pushed down toward the tail end of the outer tube, the leading end portion of the guidewire 3 is forced out in a manner folded backwardly from the leading end of the outer tube because the leading end of the guidewire 3 is secured by a string 6 to the base of the obliquely cut end 5 of the outer tube, causing the guidewire 3 to form a loop of a size corresponding to the extent of the push given to the rear portion 3' outside the leading end of the outer tube. When the rear portion 3' is pulled away from the rear end of the outer tube after the guidewire 3 has formed the loop, the exposed leading end portion of the guidewire retracts into the leading end portion of the outer tube and the loop 4 gradually diminishes and eventually disappears. The obliquely cut end 5 formed at the leading end of the outer tube 2 facilitates the formation of the loop of the guidewire mentioned above and the smooth retraction of the formed loop. The cut end is so formed as to allow easy insertion of the catheter through a hole incised in the vein via the cepharic vein into the right atrium. What is most important about the cut end of the outer tube is the fact that the leading end of the guidewire is tied to one lateral side of the leading end of the outer tube. When the guidewire 3 is composed of a covering tube 3a and a fine steel wire 3b passing through the covering tube and the leading end of the fine steel wire 3b is fastened to the covering tube 3a as in the case of the present preferred embodiment, the formation of the loop and the retraction of the formed loop can be facilitated by causing the leading end of the fine steel wire to be fixed onto the covering tube slightly back from the leading end of the covering tube so that the leading end portion of the guidewire is formed solely of covering tube and, therefore, is allowed to enjoy great freedom of flexing.

The inspection catheter is provided outside the leading end portion of the outer tube 2 with a pair of electrodes 9a, 9b. These electrodes 9a, 9b can be formed by having conductive pieces tightly wound on the outer surface of the outer tube 2, for example. In the present preferred embodiment, lead wires

10a, 10b connected respectively to the electrodes 9a, 9b extend backwardly in the wall of the outer tube 2 and drawn out of the tail end of the outer tube 2. To the rear ends of the lead wires 10a, 10b are optionally attached suitable connectors 11a, 11b for electrical connection to a measuring instrument. The aforementioned lead wires 10a, 10b are not necessarily required to be extended in the wall of the outer tube 2. They may be extended on the outer surface of the outer tube or they may be extended inside the hollow interior of the outer tube in such a way as not to interfere with the sliding of the guidewire. The portions of the lead wires 10a, 10b which are drawn out of the tail end of the outer tube 2 may be covered with an insulating coat and the portions where the lead wires depart from the tail end may be wrapped in an insulating tape 10 as occasion demands.

The fixation of the pacemaker electrodes to the endocardium of the right atrium of a given patient by means of the inspection catheter of this invention is carried out by the following procedure.

As described previously, a local incision is formed directly below the center of the patient's clavicle, and the catheter 1 is inserted through the subclavian vein into the right atrium RA until the aforementioned electrodes 9a, 9b provided at the leading end portion of the outer tube 2 comes into contact with the endocardium of the right atrium RA (Figure 5). The rear ends of the lead wires 10a, 10b are connected to an external instrument for the measurement of endocardial potential of the right atrium. Further, the rear ends of the lead wires 10a, 10b are connected to an extracorporeal pacemaker so as to forward electric current to the right atrium and measure the electrical stimulating threshold of the right atrium. The measurement of the endocardial potential and the measurement of the electrical stimulating threshold are continued while the leading end portion of the catheter is moved about inside the right atrium and the electrodes 9a, 9b are consequently brought into contact with various regions of the endocardium of the right atrium. In this manner, the optimum position for the fixation of the pacemaker electrodes is determined.

After the optimum position has been determined, the movement of the catheter is discontinued and the leading end portion thereof is kept at the optimum position. Then, the rear portion of the guidewire 3 is pushed down into the outer tube 2 so that the leading end portion of the guidewire forms a loop 4 of a desired size at the leading end of the outer tube inside the right atrium as described previously (Figure 6). Subsequently, a skin incision of approximately 2 cm is formed at the righthand extremity of the sternum in the fourth intercostal space. Through this skin incision, a double lumen needle 12 is pierced in the direction of the center of the loop 4 of the guidewire formed inside the right atrium under fluoroscopic obervation until the leading end of the needle reaches a point just in front of the loop.

Thereafter, a doubly folded induction steel wire 13 used for the fixation of the pacemaker electrodes is inserted, with the folded end first, into the double lumen needle 12 until the folded end of the induction steel wire 13 passes the vicinity of the center of the loop 4 inside the right atrium (Figure 7). After that, the guidewire 3 is pulled backwardly relative to the outer tube 2 so as to contract the loop 4. Eventually, the guidewire 3 is retracted via the leading end of the outer tube, with the result that the induction steel wire 13 is caught fast between the leading ends of the guidewire 3 and the outer tube 2 (Figure 8). Then, the catheter is completely extracted from the subclavian vein (Figure 9), so that the firmly gripped end of the induction steel wire 13 is drawn out of the body. At this point, the catheter is released from the induction steel wire 12. Now, the leading end of an endocardial lead 14' which has a pervenous electrode 14 disposed in an exposed state on the outer surface of the leading end thereof is connected with a sutural thread to be induction steel wire 13 (Figure 10), and rear end portion of the induction steel wire 13 protruding from the exposed end of the double lumen needle 12 is pulled away from the needle 12 so as to draw the endocardial lead 14' into the interior of the right atrium (Figure 11). As the result of the pull of the induction steel wire 13, the induction steel wire is first drawn out of the double lumen needle 12 and a part of the thread 15 is drawn out of the needle 12 subsequently. Shortly thereafter, the pull of the thread 15 through the double lumen needle 12 comes to a halt when the leading end of the endocardial lead 14' connected to the sutural thread collides into the leading end of the double lumen needle 12 which passes into the cavity of the right atrium. At this point, the double lumen needle 12 is drawn out of the patient's body. Then the thread 15 is sutured on the subcutaneous tissue at the righthand extremity of the sternum in the fourth intercostal space. A pacemaker 16 is connected to the end of the endocardial lead 14' is implanted in the chest wall (Figure 12).

Since the inspection catheter 1 forms the loop at a predetermined optimum position and the double lumen needle 12 is pierced in the direction of the center of the loop, the pervenous electrode 14 disposed at the leading end of the endocardial lead 14' which has been drawn by the induction steel wire 13 and the sutural thread 15 and brought into collision ith the leading end of the double lumen needle will consequently come into contact with the endocardium of the right atrium at or near the optimum position determined in advance by the inspection catheter.

According to the present invention, therefore, the pacemaker pervenous electrodes can be fixed at the optimum position determined in advance on the endocardium of the right atrium by having the electrodes 9a, 9b disposed as close to the leading end of the outer tube 2 as permissible. Since the determination of the optimum position for the fixation of the pervenous electrode and the fixation of the pervenous electrode at that predetermined optimum position are realized by having the inspection catheter inserted just once into the right atrium, the time and labor required for the attachment of the pacemaker can be notably saved by the method of the present invention.

In a preferred embodiment described above, one

pair of electrodes 9a, 9b are used and the measurement of endocardial potential and that of stimulating threshold are effected by suitably switching the connection of the lead wires 10a, 10b. Instead, there may be incorporated two pairs of electrodes, one of the two pairs used for the measurement of endocardial potential and the other pair for the measurement of stimulating threshold.

Although the present invention has been described with reference to one illustrated preferred embodiment, it is not limited to this preferred embodiment but may be practiced in various modifications without departing from the spirit of this invention.

CLAIMS

1. A method for the fixation of a pervenous electrode of an atrial pacemaker in the right atrium, which method comprises:

inserting into the right atrium of a given patient an inspection catheter composed of a slender outer tube and a guidewire slidably built in the outer tube and connected to the leading end of the outer tube and operating the inserted catheter to explore the endocardium of the right atrium and detect the optimum position for the pervenous electrode,

causing the guidewire, subsequently to the detection of the optimum position, to be pushed out of the leading end of the outer tube and allowed to form a loop inside the right atrium,

piercing a double lumen needle through the chest wall in the direction of the loop formed of the guidewire until the leading end of the needle reaches a point directly in front of the loop, inserting a doubly folded induction steel wire through the double lumen needle with the folded end first until the folded end of the induction steel wire passes through the loop inside the right atrium,

drawing the guidewire back through the outer tube to contract the loop and finally catch firm hold of the inserted end of the induction steel wire and drawing the inspection catheter completely out of the patient's body together with the induction steel wire caught fast at the end of the outer tube,

releasing the inspection catheter from the induction steel wire, tying to the leading end of the induction steel wire a sutural thread disposed at the leading end of a pervenous electrode, and pulling outwardly the outer ends of the induction steel wire remaining on the outer side of the double lumen needle so as to introduce the pervenous electrode into the interior of the right atrium and pull the sutural thread out of the double lumen needle,

removing the double lumen needle from the chest wall and subsequently suturing the sutural thread on the subcutaneous tissue for thereby fixing the pervenous electrode in the endocardium of the right atrium.

2. An inspection catheter, which comprises a long slender outer tube and a guidewire having a length greater than that of the outer tube slidably passing through the outer tube with the leading end thereof connected to the leading end of the outer tube so that when the rear portion of the guidewire protruding from the tail end of the outer tube is pushed down into the outer tube, the leading end portion of the guidewire is pushed out of the leading end of the outer tube and allowed to form a loop for catching hold of a doubly folded induction steel wire serving to guide a pervenous electrode into the right atrium, the outer tube being provided on the outer surface at the leading end thereof with at least one pair of electrodes connected to the leading ends of lead wires extended toward the tail end of the outer tube.

3. The inspection catheter according to claim 2, wherein the lead wires connected to the leading ends of the electrodes extend backwardly in the wall of the outer tube and pass out of the wall at the tail end of the outer tube to be connected to external terminals.

4. An inspection catheter as claimed in claim 2 or claim 3 and substantially as herein described with reference to the accompanying drawings.

5. A method as claimed in claim 1 and substantially as herein described with reference to the accompanying drawings.

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